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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,976	10/02/2000	Michael E. Kafrissen	ORT-1316	7964

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/677,976	KAFRISSEN ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/31/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the risk of pregnancy, does not reasonably provide enablement for prevention of pregnancy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to a method of administering folic acid to a subject for whom an oral contraceptive is indicated for preventing pregnancy by administering in a pharmaceutical composition which comprises an oral contraceptive for preventing pregnancy and folic acid sufficient to reduce the risk of cervical displasia or cervical carcinoma.

The state of the prior art and the predictability or lack thereof in the art:

The prior art discloses the use of oral contraceptives for reducing the risk of pregnancy and 100% reduction in risk is not disclosed. As such, predictability as to prevention is low.

The amount of direction or guidance present and the presence or absence of working examples:

Although Applicant uses the term "prevention" with respect to pregnancy in the Specification, Applicant admits that women taking oral contraceptives can and do become accidentally pregnant (Response (10/31/2005)).

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that claims indicate that pregnancy can be prevented. However, Applicant admits that pregnancy cannot be completed prevented by the use of oral contraceptives. As such, it appears that one of ordinary skill in the art would be required to due experimentation in order to develop an oral contraceptive which prevents pregnancy.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schubring (Abstract) in view of Bamji et al. (Abstract), US Pat. 5,254,572 (Serfontein), Bielenberg (Abstract), Harper et al. (Abstract), Check (Medical News) and Drug Facts and Comparisons (1994).

Schubring discloses the combination of oral contraceptives with pyridoxine and folic acid and that oral contraceptives causes drops of folic acid levels and vitamin B6 deficiency (pgs. 1045,1047).

Bamji et al. discloses that in view of the high prevalence of vitamin deficiency, including folic acid deficiency and vitamin B6, the delivery system for oral contraceptive can be effectively used for giving vitamin supplements as well (Abstract).

Serfontain discloses the use of oral contraceptives can result in vitamin B6 deficiency and that the vitamin B6 can be supplemented by the combination of vitamin B6 and oral contraceptive in a single dosage form (Column 19, Column 20, lines 1-40).

Bielenberg discloses that oral contraceptives can induce folic acid and vitamin B deficiency (Abstract).

Harper et al. disclose that folate depletion is a risk factor for cervical dysplasia (Abstract).

Check (Medical News) discloses that folic acid supplementation may help reduce the risk of cervical cancer in women taking combination oral contraceptive agents (Pg. 633).

Drug Facts and Comparisons discloses that the recommended daily allowance for folic acid for adults is 0.4 mg (Pg. 232).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method for reducing the risk of cervical dysplasia or carcinoma by administering in a single dosage form the combination of oral contraceptive and folic acid. However, the prior art amply suggests the same in that the prior art discloses the oral contraceptives can be combined with folic acid and pyridoxine, that oral contraceptives cause folic acid and pyridoxine depletion, that Vitamin B6 can be combined with oral contraceptives in a single dosage form and that folic acid supplementation can reduce the risk of cervical dysplasia or carcinoma in women taking oral contraceptives. As such, it would have been well within the skill of and one of ordinary skill in the art to combine folic acid and oral contraceptives in a

single dosage form and administer said dosage form with the expectation that the folic acid contained therein would reduce the risk of cervical dysplasia or carcinoma.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The fact that the example disclosed in Schubring does not disclose folic acid and oral contraceptive in a single dosage form does not teach away from the claimed invention. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971). Bamji also suggests continuous vitamin supplementation. The claims are not limited to methods of supplementing folic acid in women who accidentally become pregnant while taking oral contraceptives. There is no requirement that '572 teach or suggest a method for administration of folic acid. The '572 patent discloses the combination of a vitamin, in this case vitamin B6, and oral contraceptives. Since vitamin B6 and folic acid deficiency can occur with oral contraceptive administration. It would be well within the skill of and one or ordinary skill in the art to substitute one vitamin for another or combine the vitamins with the expectation that since vitamin B6 deficiency can be treated with the combination and that separate continuous supplementation with folic acid can treat folic acid deficiency, that combined folic acid and oral contraceptive in a composition would be effective for treating folic acid deficiency caused by the oral contraceptive. The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed.

Cir. 1992). See also In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); In re Eli Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); In re Nilssen, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings);and Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning).

The prior art discloses that women who take oral contraceptives are deficient in folic acid regardless of whether they become pregnant or not while taking oral contraceptives. As such, since it is known in the art to combine a vitamin, albeit a different vitamin, with oral contraceptives in the same pill, there is amply motivation to combine folic acid with oral contraceptives in a single pill. Applicant claims, in any case, are not limited to women who become accidentally pregnant while taking oral contraceptives. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) .

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's admission, as indicated above, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
January 23, 2006

SABIHA QAZI, PH.D
PRIMARY EXAMINER